



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

NOV - 3 2000

Mr. Siddharth Shastri  
Vice President, Director of Product Development  
Jarrow Formulas, Inc.  
1824 South Robertson Boulevard  
Los Angeles, CA 90035-4317

*Rec'd  
Nov 15 2000  
16*

Dear Mr. Shastri:

This is in response to your letter of October 18, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Jarrow Formulas, Inc. is making the following claim, among others, for the product PS-100:

“...Age-associated cognitive decline (AACD) and compromised brain function....

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

975-0163

LET 417

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson)

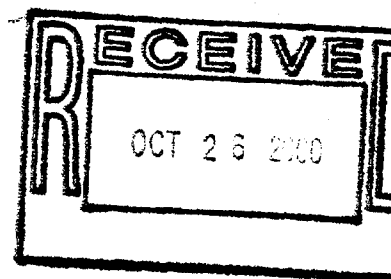
f/t:HFS-811:rjm:10/30/00:docname:73067.adv:disc51

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Fax Numbers  
Orders 800/890-8955  
General 310/204-2520  
Administrative 310/204-5132

Division of Compliance and Enforcement/ONPLDS  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
HFS-810  
200 C Street, S.W.  
Washington, DC 20204  
202-205-5229

October 18, 2000



Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

**(1) Name of Address of distributor:**

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

**(2) Text of the statement(s):**

"Promotes Brain Function" – Age Associated Cognitive Decline (AACD) and compromised brain function begin at the onset of middle age and are commonly associated with decreased levels of phosphatidylserine (PS).

**(3) Name of the dietary ingredient(s) if not provided in the text of the statement:**

Phosphatidylserine

**(4) Name of the dietary supplement(s)**

PS-100 – 100 mg 60 capsule size

PS-100 – 100 mg 120 capsule size

PS-100 – 100 mg 30 softgel size

PS-100 – 100 mg 30 softgel size

**(5) The following disclaimer appears on the label in bold:** These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients. A compendium of relative published research substantiating the above statement(s) is on file at the corporate office.

Respectfully submitted,

Siddharth Shastri, CCN

Vice President, Director of Product Development  
Licensed Dietitian/Clinical Nutritionist, #002378  
(by the University of the State of New York, State Board of Education)  
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